By Royal Charter

UKCA Certificate - Production Quality Assurance

Part II of The Medical Devices Regulations 2002, Annex V [as modified by Part 2 of Schedule 2A to The Medical Devices Regulations 2002]

No. **UKCA 810198**

Issued To: **GM Instruments Ltd**
Greig House
Block 1 Annickbank Innovation Campus
Annick Road
Irvine
KA11 4LF
United Kingdom

In respect of:

Manufacture and final inspection of active diagnostic devices including software for Audiometry.

On the basis of our examination of the quality assurance system under the requirements of Part II of the Medical Devices Regulations 2002, Annex V [as modified by Part II of Schedule 2A to The Medical Devices Regulations 2002]. The quality assurance system meets the requirements of the regulation. For the placing on the market of class IIb and class III products an Annex III certificate (modified as described above) is required.

For and on behalf of BSI, an Approved Body for the above Regulation (Approved Body Number 0086):

Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

First Issued: **2024-05-24** Date: **2024-05-24** Expiry Date: **2025-12-18**

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Supplementary Information to UKCA 810198

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Annick Road
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NBOG code(s)	Device description	Intended purpose per IFU
Class IIa		
MD 1103 MD 1111	Audiometer including associated standalone software	NA for class IIa devices

First Issued: **2024-05-24** Date: **2024-05-24** Expiry Date: **2025-12-18**

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UKCA Certificate - Production Quality Assurance Certificate History

Certificate No: **UKCA 810198**
Date: **2024-05-24**
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Date	Reference Number	Action
Current	30186099	First Issue; Traceable to CE 717656.

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